

Job Description

Job title:	QA Officer
Reports to:	Quality Assurance Director
Department:	Quality
Job type:	Full time (permanent)
Work location:	Waterloo, London (office based)

About uMotif

uMotif's mission is to put patients at the centre of research by building data capture solutions people love to use. Designed with patients for patients, the uMotif platform supports data capture for each phase of clinical research across all therapeutic areas. Over 22,000 participants use our applications to track and submit e-consent, symptom, eCOA, ePRO, and wearable device data. With expertise in engaging patients and fast deployments, we work with 10 of the top 20 global pharmaceutical companies to power large real-world evidence (RWE) and virtual studies.

Job Summary

The QA Officer is responsible for assisting with the management of the quality systems used to ensure all impacted computerised systems are maintained in a validated state in accordance with the requirements of GxP rules, regulations and guidelines, and industry standards. The QA Officer works with the QMS Specialist and other departments to prepare, review, and maintain quality policies, and procedures, associated with the qualification and validation of computerised systems for the pharmaceutical and medical device industries.

Responsibilities

Quality Management System (QMS) - to follow, review, and assist with improvements to the QMS, ensuring the following activities are carried out:

- Implementing and maintaining policies to control the validation of software applications and the qualification of cloud based infrastructure in a software development environment

QA Operations - to assist the delivery of the following activities:

- Perform due diligence checks and ensure service and software product suppliers are qualified

- Perform quality activities associated with Computer System Validation (CSV) and Quality Risk Management for computerised systems in a software development environment
- Review and approve changes to computerised systems through the change control process to assess the impact on the validated state
- Ensure that, where required, software applications are validated according to current regulatory requirements
- Facilitate the drafting, approval, execution, and reporting of validation documentation as required
- Assist with the qualification of IT infrastructure, as implemented in a cloud computing architecture, according to current regulatory requirements
- Provide quality support during the definition of what qualification/validation stages are required for software applications and hardware infrastructure to ensure compliance with GxP rules, regulations, and guidance
- Provide quality support as required to facilitate investigation and resolution of testing deviations associated with the qualification and validation of uMotif software and infrastructure solutions
- Assist with customer / regulatory audits as required
- Focus on the accuracy and quality of records associated with the QMS ensuring record entries are done on a contemporaneous basis and that records are stored appropriately
- Assist with performance of periodic reviews of the validation and qualification status of computerised systems. This will include uMotif software and infrastructure solutions, and third party software used as part of the software development life cycle
- Assist with the resolution of Corrective and Preventative Actions (CAPA) to ensure appropriate investigations are carried out and remedial actions implemented in a timely manner
- Assist with generating QMS indicator metrics for review by management
- Assist with developing processes to facilitate uMotif obtaining a 'CE' mark status

Information Privacy and Security – to maintain the following:

- Documentation associated with information governance in a current state
- Documentation associated with HIPPA requirements in a current state

Requirements

- Computer literate, e.g. Microsoft Word, Excel, PowerPoint, Project, and Visio
- Graduate in Life-Sciences subject (e.g. Chemistry, Biology, Pharmaceutical Sciences, Pharmacy...) or a Computer Sciences discipline
- 3yrs+ experience of applying quality systems and computer system validation strategies in regulated software development industries

- Build and maintain solid working relationships and communication links within uMotif Ltd. and third-party contractors
- Maintain competence in GxP via self-learning, intercompany collaboration, and attend appropriate external training courses and seminars
- Good Clinical Practice (GCP) knowledge
- Knowledge of ISPE GAMP 5 - A Risk-Based Approach to Compliant GxP Computerized Systems
- Knowledge of Quality System, Medical Device regulations would be an advantage (e.g ISO9001, ISO13485)

Nice to have

- Able to practice continuous improvement and utilize tools and techniques to solve problems
- Good project management skills and able to prioritise work plans and an ability to multitask
- Knowledge of the 'Agile' methodology of software development

What we offer

- 25 days holiday per year, plus an additional day off for your birthday
- Bupa private medical insurance
- Workplace pension contribution
- Share options
- 'uToken' annual lifestyle bonus
- Flexible working hours
- Training and personal development contribution
- Cycle to work scheme

How to apply

Click the "Apply" button on the uMotif Careers webpage for the appropriate role. Attach your CV and a cover letter including a statement to confirm you consent to uMotif holding your CV for a duration of the current recruitment phase.

uMotif is an equal opportunities employer and positively encourages applications from suitably qualified and eligible candidates regardless of sex, race, disability, age, sexual orientation, gender reassignment, religion or belief, marital status, or pregnancy and maternity.

We are looking for the successful candidate to start as soon as possible and applications will be considered in the order they are received. No recruiters.